M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

22 AM 10:12

Date: February 2, 2000

To: Dockets Management Branch (HFA-305)

From: Melissa Lamb
Office of Generic Drugs

Subject: Current OGD Issues (Life after Doug)

This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records:

Title of Presentation: Current OGD Issues (Life after Doug)

Presented for: NAPM 2000 Annual Meeting

Date Presented: 2/2/2000

Presented by: Gary J. Buehler

Number of Pages: 17

Melissa Lamb

Attachment

90S-0308

M669

NAPM 2000 Annual Meeting

Current OGD Issues (Life After Doug)

Gary J. Buehler, Deputy Director
Office of Generic Drugs
February 2, 2000
Rio Grande, Puerto Rico

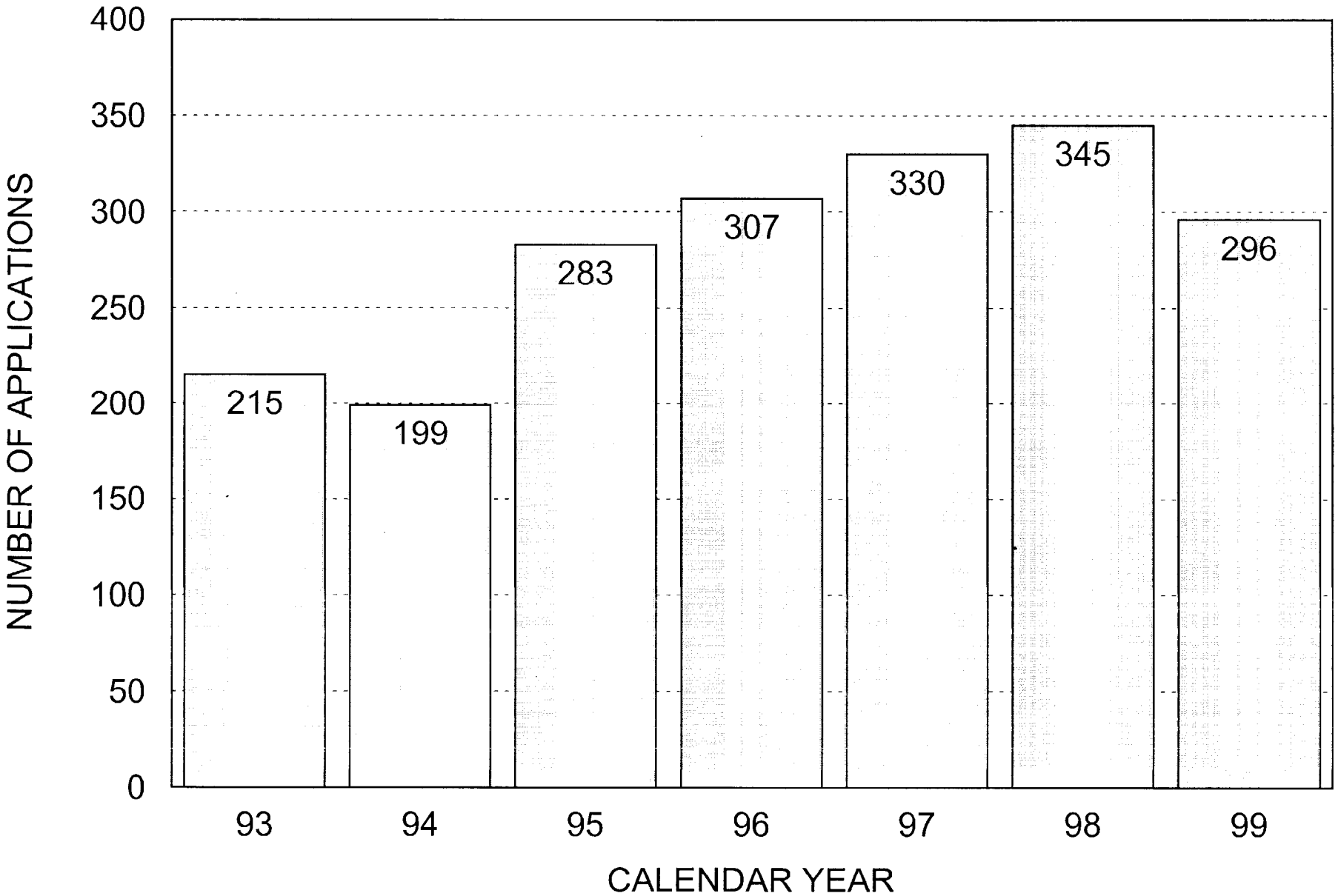
- Priorities
- OGD Year End Review
- New Compliance Policy
- DSI Inspections
- Reserve Samples

Priorities

- Productivity
- Guidance Development
- Electronic Submissions
- Resources

OGD Year End Review

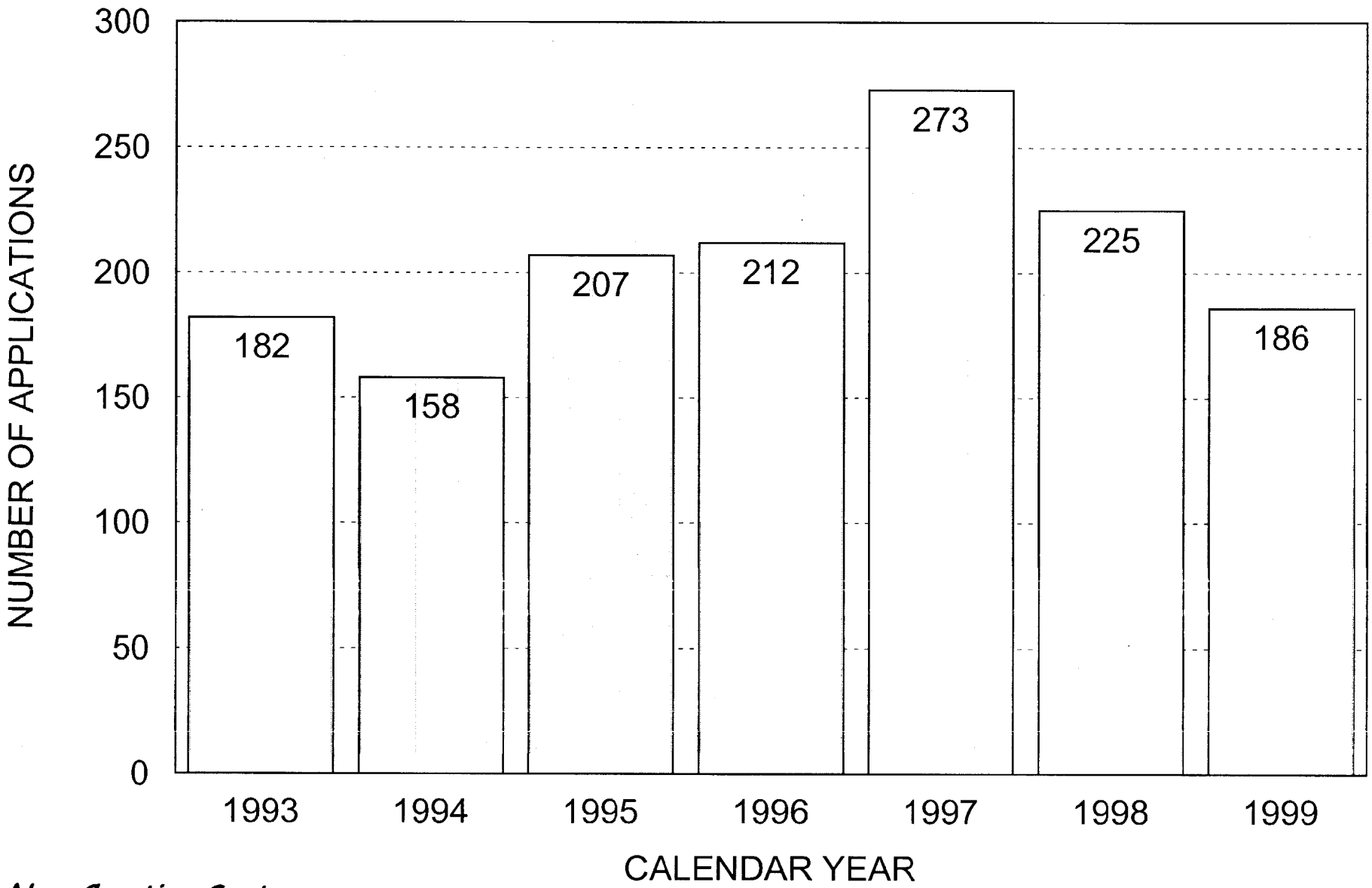
Calendar Year Receipts



New Counting System

December 31, 1999

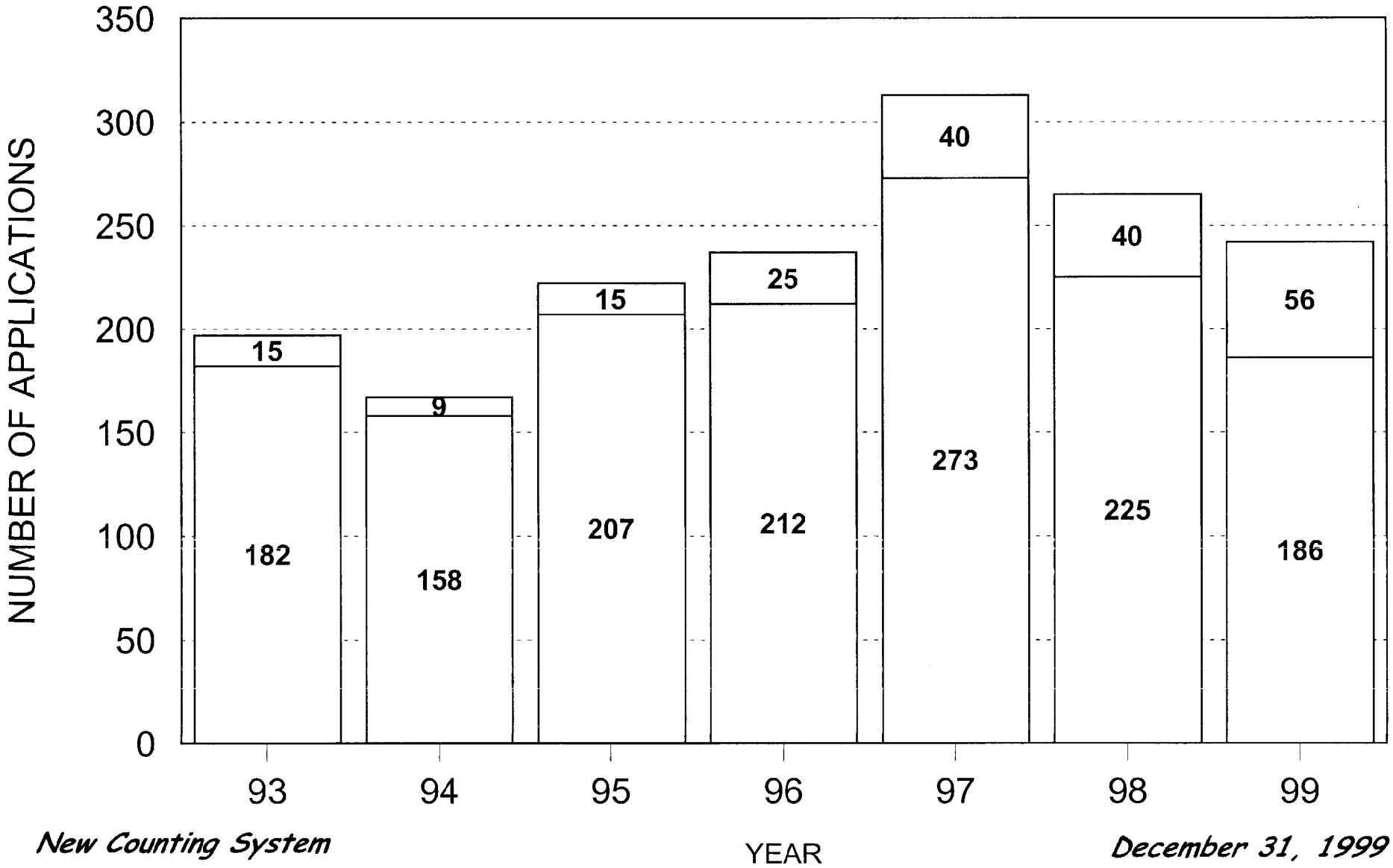
Calendar Year Approvals



New Counting System

December 31, 1999

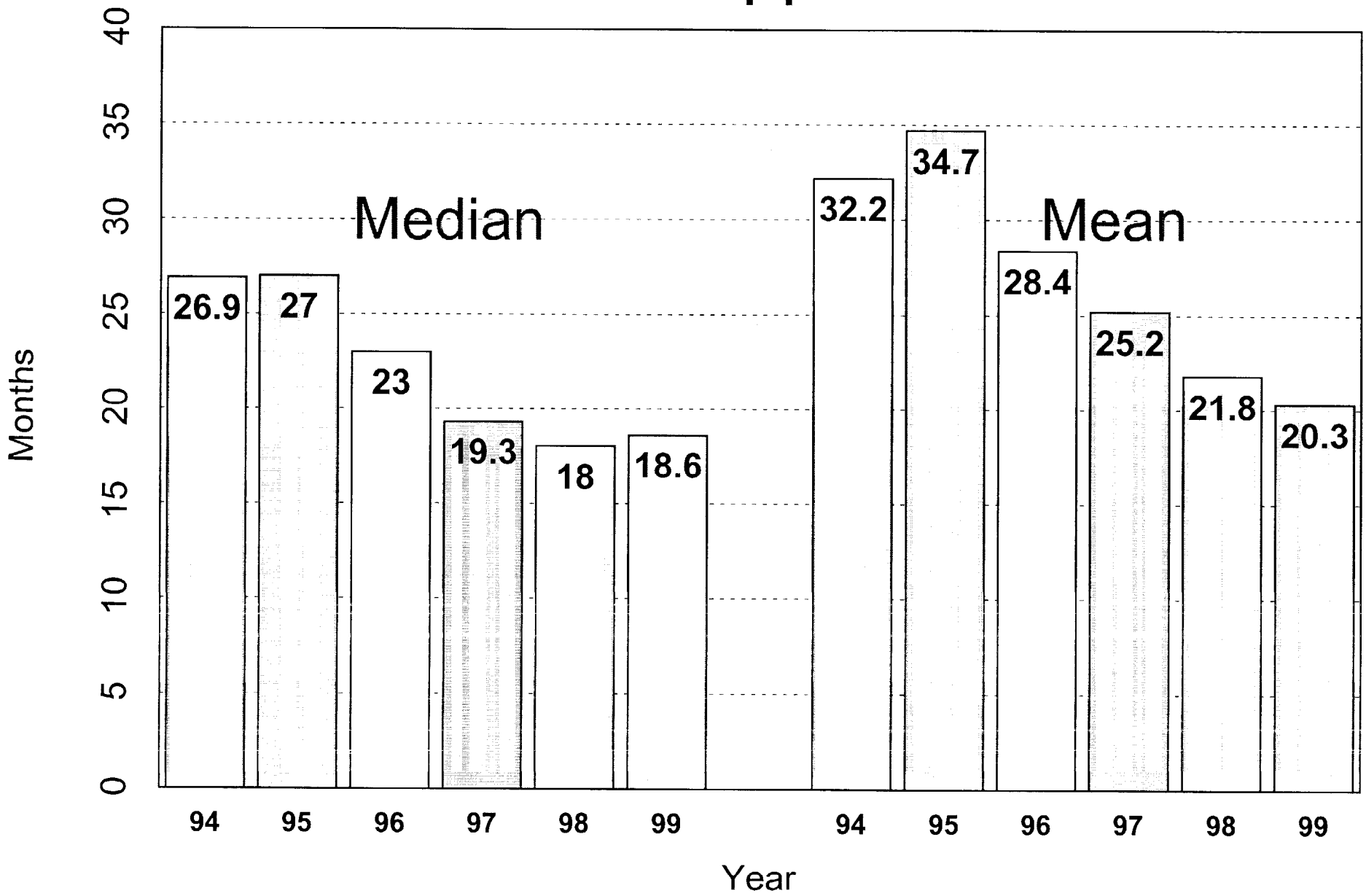
Calendar Year Approvals & Tentative Approvals



New Counting System

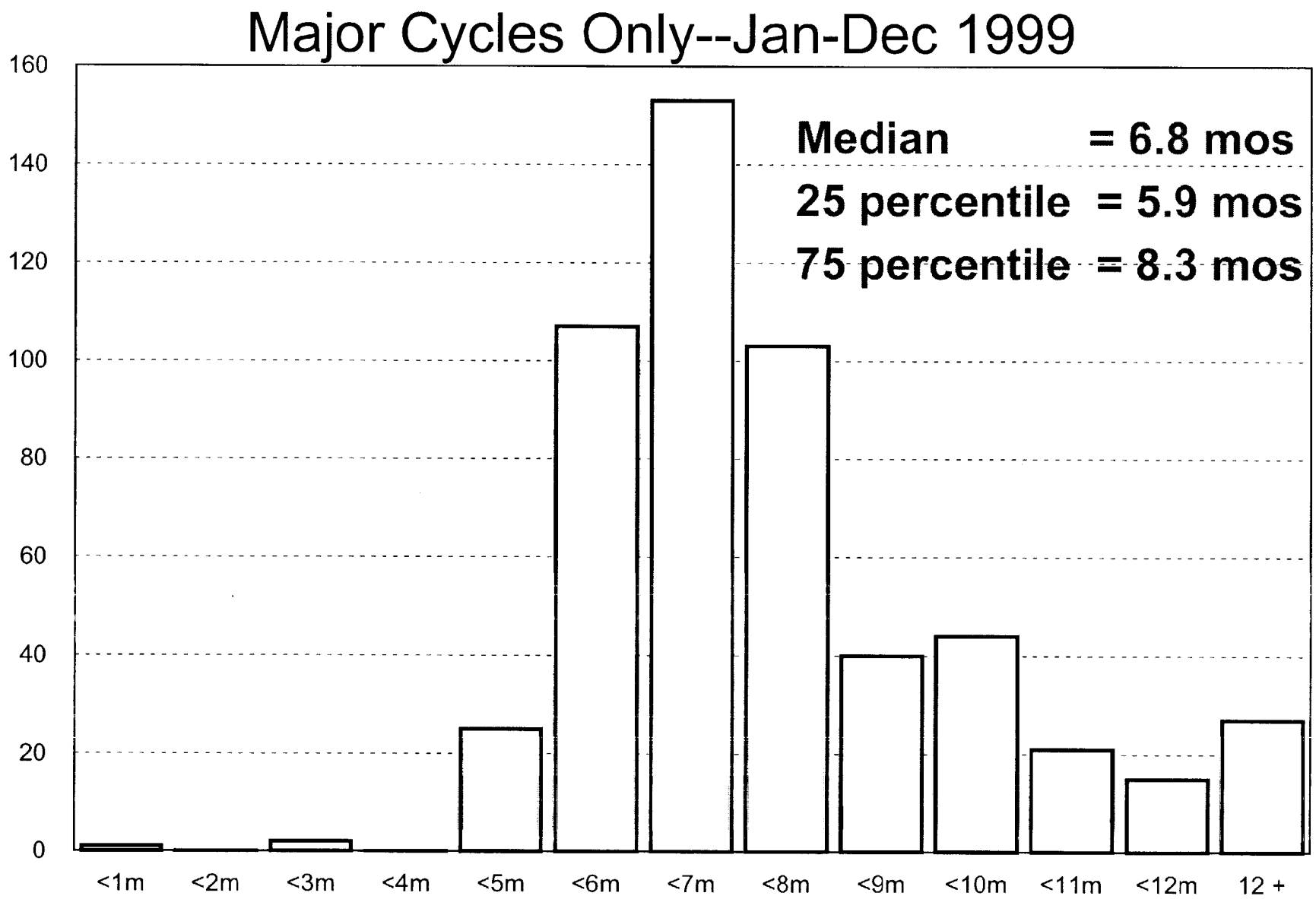
December 31, 1999

Calendar Year Approval Times



December 31, 1999

Distribution of Review Times for Original ANDAs



OGD Personnel by Discipline

	FY 99 Ceiling	Change
Chemistry Reviewers	49	+2
Bioequivalence Reviewers	26	+1
Project Managers/Technician	15	+4
Clerical	9	+2
Labeling Reviewers	11	+1
Management/Admin. Support	9	
Microbiologists	4	+1
Application Examiners	2	
Medical Officer	1	
Computer Specialist	2	
Statistician	1	
Total	129	140

- Relatively New Staff
  - Micro Reviewers: 75% ≤ 1 Yr
  - Chemistry Reviewers: 20% ≤ 1 Yr
  - Project Managers: 50% ≤ 1 Yr

Location Changes

2002 - Some CDER Offices relocate to:

Site of former Naval Surface Warfare Center - White Oak

Silver Spring, MD

New Compliance Policy

- The Office of Compliance, Division of Manufacturing and Product Quality has extended the period of acceptability of Establishment Evaluation Requests under the Pre-Approval Inspection Program from 1 to 2 years

New Compliance Policy

- Decision is retroactive as long as the follow up request (FUR) inspection has not begun

Division of Scientific Investigations (DSI) Study Audits

- To conserve inspection resources, priorities have been established:
  - Non-conventional study for which study site has never been inspected
  - Testing site has no inspection history or was classified OAI in its last inspection
  - Directed Inspection - Question of quality or integrity of data
  - 1st Generic

Reserve Samples

- 21 CFR 320.32 and 320.63 Discusses Retention of Bioavailability and Bioequivalence Samples
  - Applicant or CRO shall retain an appropriately identified reserve sample (test article and RLD).
  - Each reserve sample shall consist of a sufficient quantity to permit FDA to perform 5 times all of the required tests.
  - Samples shall be stored under conditions that will maintain sample's integrity, identity, strength, quality, and purity for 5 years.

Reserve Samples - Other Issues

- Samples for testing must be randomly selected from the supplies provided. (Not a separate bottle for reserve samples)

- If CRO closes, samples must be transferred to a third party for storage